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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,131	11/07/2005	John P. Maye	61843USN(51035)	2561
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EXAMINER				
FLOOD, MICHELE C				
ART UNIT		PAPER NUMBER		
1655				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/529,131

Applicant(s)

MAYE, JOHN P.

Examiner

MICHELE FLOOD

Art Unit

1655

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on August 18, 2009.

Any rejection set forth in the previous Office action mail dated February 18, 2009 and not repeated herein is withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 11 and 12 are under examination.

Response to Arguments

Claim Objections

Claim 12 is objected to because of the following informalities: Claim 12, line 5 recites the limitation "wherein the aqueous alkali solution of hop acids are mixed"; and, therefore there is no agreement between the noun and the verb recited in the claim language. Applicant may overcome the objection by replacing "are" with is. Newly applied as necessitated by amendment.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 11 and 12, as amended, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The claims are rejected for failing to provide prior support or antecedent basis for the language "aqueous alkali solution of hop acids" in Claims 1, 2, 5, and 12. Newly applied as necessitated by amendment.

Claim 1, as set forth in the amendment filed on August 18, 2009, now recites "A method of preparing an organic food supplement useful to inhibit *Ruminococcus albus*, *R. flavefaciens*, *Butyrivibrio fibrisolvens*, or *Methanobacterium ruminatum* for livestock comprising mixing an aqueous alkali solution of hop acids for oral ingestion with a livestock feed wherein the aqueous alkali solution of hop acids are mixed with the feed in an amount to inhibit undesirable bacteria selected from the group consisting of *Ruminococcus albus*, *R. flavefaciens*, *Butyrivibrio fibrisolvens*, and *Methanobacterium ruminatum*, commonly found in digestive systems of livestock".

Claim 2, as set forth in the amendment filed on August 18, 2009, now recites "The method of claim 1 wherein the hop acids from the aqueous alkali solution of hop

acids are selected from at least one of the group consisting of alpha acids, beta acids, isoalpha acids, rho-isoalpha acids, tetrahydroisoalpha acids and hexahydroisoalpha acids".

Claim 5, as set forth in the amendment filed on August 18, 2009, now recites "The method of claim 1 wherein the hop acids from the aqueous alkali solution of hop acids mixed with the feed results in an amount of 2 parts per million (ppm) of hop acid present in fluid of the digestive systems of livestock".

Claim 12, as set forth in the amendment filed on August 18, 2009, now recites "The method of claim 1 wherein an amount of hop acids from the aqueous alkali solution of hop acids mixed with the feed is capable of increasing a level of propionate in the digestive systems".

However, the specification as originally filed provides only for a method of preparing an organic food supplement useful to inhibit claim-designated microorganisms for livestock comprising mixing hop acids with a livestock feed.

Insertion of the mentioned claim limitations has no support in the as-filed specification. The insertion of the limitations is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of a method of preparing an organic food supplement useful to inhibit *Ruminococcus albus*, *R. flavefaciens*, *Butyrivibrio fibrisolvens*, or *Methanobacterium ruminantium* for livestock comprising mixing an aqueous alkali solution of hop acids for oral ingestion with a livestock feed wherein the aqueous alkali solution of hop acids are

mixed with the feed in an amount to inhibit undesirable bacteria selected from the group consisting of *Ruminococcus albus*, *R. flavefaciens*, *Butyrivibrio fibrisolvens*, and *Methanobacterium ruminantium*, commonly found in digestive systems of livestock. There are only two exemplified methods for preparing the claim-designated livestock feed comprising mixing beta acids with barley as set forth in Example 4, on page 5 of the specification or comprising mixing alpha acids or beta acids with alfalfa, as set forth in Example 7, on pages 7 and 8. This is not sufficient support for the new genus: "aqueous alkali solution of hop acids". This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim limitations is considered to be the insertion of new matter for the above reasons.

As the above-mentioned claim limitations could not be found in the present specification, the recitation of the claim limitations is deemed new matter. In the REMARKS" (last two lines of page 8) filed on August 8, 2009, Applicant asserts that support for amended Claim 1 to include an aqueous alkali solution of hops acids can be found at least at Examples 10 and 11 of the specification. However, nowhere in the passages of Example 10 did the Office find support for the claim limitation and there is no Example 11 in the as-filed specification; and, therefore it must be omitted from the

claim language, unless Applicant can particularly point to the specification for literal support.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-5 and 12, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

Each of Claims 2 and 5 recites the limitation "the hop acids from the aqueous alkali solution of hop acids" in lines 1-2. There is a lack of clear antecedent basis for this limitation in the claims, as there is no 'hop acids from the aqueous alkali solution of hop acids' *per se*.

The metes and bounds of Claim 12 are rendered vague and indefinite by the limitation, "wherein an amount of hop acids from the aqueous alkali solution of hop acids mixed with the feed is capable of increasing a level of propionate in the digestive systems", because the scope of Claim 1 (from which Claim 12 directly depends) encompasses subject matter directed to "mixing an aqueous alkali solution of hop acids for oral ingestion with a livestock feed" to provide a method of preparing an organic food supplement useful to inhibit *Ruminococcus albus*, *R. flavefaciens*, *Butyrivibrio fibrisolvens*, or *Methanobacterium ruminatum* for livestock, which is different from

mixing an amount of hop acids from or obtained or isolated from the aqueous alkali solution used in the making of the organic food supplement which has the functional effect of increasing a level of propionate in the digestive systems of livestock. Thus, it is uncertain as to what is the subject matter to which Applicant seeks patent protection since it is unclear as to what amount of hop acids from the aqueous alkali solution of hop acids mixed with the feed is an amount capable of increasing a level of propionate in the digestive systems. The lack of clarity renders the claim very confusing and ambiguous.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE FLOOD whose telephone number is (571)272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
December 4, 2009

/Michele Flood/
Primary Examiner, Art Unit 1655